

June 18, 2004

Dr. Barbara Shane,
NTP Executive Secretary
NIEHS
P.O. Box 12233
MD A3-01
Research Triangle Park, NC 27709

Re: Comments on the talc nominations for the 12th RoC

Dear Dr. Shane and Distinguished Counselors:

Luzenac America has been a leading producer of high quality talc products for nearly a century and we presently account for over 50% of the talc mined and milled in the United States. All the talc products sold by Luzenac are asbestos-free¹ and contain less than 1% crystalline silica. Naturally, the National Toxicology Program's (NTP) nominations for the 12th RoC listing of "talc" in the form of "Cosmetic talc" and "Occupational exposure to talc" are of great concern to Luzenac and the talc industry worldwide. As such, Luzenac submits to NTP and the Board of Scientific Counselors the following objections to these talc nominations in order to allow NTP the opportunity to amend the nominations and reevaluate their merit for formal consideration by NTP.

(1) Given all the problematic issues generated during the review of the 10th RoC nominations for "asbestiform" and "non-asbestiform talc", we find it inexplicable that NTP has proposed what are essentially "exposure" nominations with no definitional criteria applied to the mineral talc itself. Given that the *key* challenge posed by a review of the literature is to differentiate exposure studies by the nature of the talc e.g., "talc not containing asbestos" or "talc containing asbestos", it is absolutely essential that these parameters be clearly established from the outset in order to permit an objective, scientific review of the talc mineral *itself*.

The Cosmetic, Toiletry, and Fragrance Association (CTFA) defines cosmetic talc as follows:

DEFINITION: "Cosmetic Talc is an essentially white, odorless, fine powder ground from naturally occurring rock ore. It consists typically of 90% hydrated magnesium silicate, having the ideal formula $\text{Mg}_6(\text{Si}_8\text{O}_{20})(\text{OH})_4$ with the remainder consisting of naturally associated minerals such as calcite, chlorite, dolomite, kaolin, and magnesite, and containing ***no detectable fibrous, asbestos minerals*** (emphasis added)."

¹ Luzenac America Product Statement: "Luzenac talc does not contain asbestos as defined by the United States Occupational Safety and Health Administration (OSHA), the European Directive 83/477/EEC, and the American Congress of Governmental Industrial Hygienists (ACGIH) when analyzed by X-ray Diffraction, Polarized Light Microscopy, or Transmission Electron Microscopy. This statement is based upon verification by certified, independent laboratories."

The CTFA definition of cosmetic talc was amended on October 7, 1976 to include the criteria “no detectable fibrous, asbestos minerals.” Additionally, the CTFA cosmetic talc specification was amended to include a specification (None detected) and test method (CTFA J4-1) for certifying the absence of asbestos in cosmetic talc.² These definitional changes were promulgated as a result of two studies, one in 1968³ and one in 1976,⁴ which reported finding fibrous-like materials and asbestos in off-the-shelf consumer body powder talc products. In the latter study, half the brands had detectable asbestos. This occurred at a time when evidence was accumulating concerning the human carcinogenicity of asbestos and thus the findings generated considerable press coverage and public concern.^{5,6} These actions by CTFA and its member companies assured the U.S. Food and Drug Administration and the public at large that exposure to cosmetic talcs (post 1976) would no longer carry the risks associated with exposure to asbestos. As such, the NTP nomination of “Cosmetic talc” must be amended to meet this CTFA definition if the RoC review is to have any relevance to current exposures of cosmetic talc.

(2) As with “Cosmetic talc”, the nomination of “Occupational exposure to talc” must be amended to “Occupational exposure to talc not containing asbestos.” Asbestos is already listed as a known carcinogen by IARC and NTP and therefore a review of the literature must exclude those studies in which asbestos in the talc (or in the surrounding overburden in studies of talc miners) is reported or suspected. A scientific review of the mineral talc *itself* cannot otherwise be conducted. However, when this definitional criteria is applied to occupational exposure, the available literature *does not* support a nomination. During the review of the 10th RoC nominations for “asbestiform” and “non-asbestiform talc, the DBD⁷ concluded;

“In the light of these findings, the evidence from studies of occupational exposure to non-asbestos-containing talc is not sufficient to support a conclusion that this form of talc is carcinogenic.”

Additionally, neither RG1, RG2, or the Board of Scientific Counselors Subcommittee found sufficient evidence to conclude that occupational exposure to “talc not containing asbestos” is carcinogenic.

² CTFA Specification, 10-7-76, “Talc Cosmetic”, Attachment 1.

³ Cralley LJ, Key MM, Groth DH, Lainhart WS, and Ligo RM. 1968. Fibrous and mineral content of cosmetic talcum products. *Am Ind Hyg Assoc J* 29 (4): 350-54.

⁴ Rohl AN, Langer AM, Selikoff IJ, Tordini A, Klimentidis R, Bowes DR, and Skinner DL. 1976. Consumer talcums and powders: Mineral and chemical characterization. *J Toxicol Environ Health* 2 (2): 255-84.

⁵ Washington Post, March 8, 1976, “Asbestos Fibers Found in Baby Powder”, Attachment 2.

⁶ New York Times, March 10, 1976, “Asbestos Found in Ten Powders”, Attachment 3.

⁷ See DBD sec, 3.3, “Talc containing asbestiform fibers and talc not containing asbestiform fibers”, at 42.

In summary, the nominations put forth by NTP for "Cosmetic talc" and "Occupational exposure to talc" are wholly inappropriate to permit a scientific review of the mineral talc itself. Both nominations must be amended to include the definitional qualifier "talc not containing asbestos." In doing so, the newly formed NIEHS/NTP RoC Nomination Committee must reevaluate the merits of the nominations to determine if there is sufficient literature to support the nominations. Evidence from the review of the 10th RoC strongly suggests otherwise.

Sincerely,



Daniel D. Harris
President
Luzenac America

Attachments

cc: Director, National Toxicology Program and NIEHS, Dr. Kenneth Olden

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ATTACHMENT 1

TALC COSMETIC

Issued: 6-1-42
Revised: 3-23-82
5-30-71
10-7-76



CTFA Adopted Name:
TALC

COSMETIC TALC

DEFINITION: Cosmetic Talc is an essentially white, odorless, fine powder, ground from naturally occurring rock ore. It consists typically of 90% hydrated magnesium silicate, having the ideal formula $Mg_3(Si_2O_5)_2(OH)_2$, with the remainder consisting of naturally associated minerals such as calcite, chlorite, dolomite, kaolin and magnesite, and containing no detectable fibrous, asbestos minerals.

TEST	SPECIFICATION	METHOD
Color	As specified by the buyer and showing no change after heating	Heat 1 to 2 g at 200°C for 5 minutes
Odor	As specified by the buyer	
Identification	Positive: 1. Close match to CTFA Spectrum—IR with no indication of foreign materials OR 2. (Alternate) Close match to X-ray Powder Diffraction File No. 19-770, published by ASTM, showing the most intense reflections at d values about 9.35, 1.53 and 4.59 Å	CTFA G 3-1 ASTM D 934-74
Slip	As specified by the buyer	
Lustre	Do.	
Water-Soluble Iron	Passes test	USP XIX, page 487
Screen Test	100% through 100 mesh 98% minimum through 200 mesh Finer grades: as specified by the buyer	CTFA C 6-1
Water Soluble Substances	0.1% maximum	USP XIX, page 487 See test for "Reaction and Soluble Substances"
Acid Soluble Substances	As specified by the buyer 6.0% maximum	CTFA E 32-1
Loss of Ignition	≤ 0% maximum	USP XIX, page 487
Arsenic (as As)	3 ppm maximum	CTFA F 1-1, Parts I-A and II
Lead (as Pb)	20 ppm maximum	CTFA F 2-1, Parts I-A and II
Fibrous Amphibole	None detected	CTFA J 4-1
(Asbestiform Tremolite et al)		
Free Crystalline Silica	As specified by the buyer	CTFA J 5-1 (DTA) Alternate: CTFA J 6-1 (X-ray)
(Quartz)		
	

Asbestos Fibers Found in Baby Powder

By Marian Burros

Washington Post Staff Writer

Asbestos fibers, which are found in thousands of products from food to building insulation, have been discovered in nine of 19 body and baby powders studied by researchers at Mt. Sinai Hospital in New York.

Asbestos can cause mesothelioma, a rare form of chest and abdominal cancer, and asbestosis, scarring of lung tissue. In 1972 Dr. William J. Nicholson of Mt. Sinai reported that these diseases caused nearly 40 per cent of the deaths of New York-New Jersey asbestos workers.

Dr. Irving J. Selikoff of Mt. Sinai, a leading expert on occupational disease, said, "We do not know a safe threshold level for a carcinogen like asbestos." Once asbestos fibers enter the body, he said, they stay there.

Researchers at Mt. Sinai's Department of Environmental Medicine tested one sample each of 19 body and baby powders. Arthur M. Langer, head of the physical sciences section of the department, said nine samples contained asbestos fibers in quantities ranging from "2 to 20 per cent."

The powders with the greatest concentration of asbestos fibers, ranging from 8 to 20 per cent, were ZBT Baby Powder with baby oil, Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc.

Bauer & Black Baby Talc, which is no longer on the market, had a 15 per cent concentration of asbestos fibers, the researchers found.

Smaller amounts of asbestos fibers—under 5 per cent—were found in Faberge Brut Talc, Yardley Invisible Talc, Yardley Black Label Body Powder, Mennen Shave Talc and English Leather After Shave Talc.

Officials of Colgate Palmolive, which makes Cashmere Bouquet, Sterling Drugs, Inc., manufacturer of ZBT Baby Powder and of Coty said they are certain their products are safe. They said no asbestos had been found in their testing.

The manufacturer of Rosemary Talc could not be reached for comment.

The other powders studied were Ammen's Medicated Powder; Avon Bird of Paradise Beauty Dust; Diaperene Medicated Body Powder; Johnson's Baby Powders, one made in England and one in the United States; Johnson's Medicated Powder; Mennen Bath Talc; Yardley After Shave Powder and Yardley Original Body Powder. None of them contained asbestos. One, Diaperene, contained no talc. It is made of cornstarch.

The Food and Drug Administration said in 1972 it would propose regulations to govern the use of asbestos-contaminated talc in cosmetics. The director of FDA's division of cosmetics technology, Heinz J. Eirmann, said recently the agency had not issued regulations because it had not found a "fast method" for determining the presence of asbestos at low levels. The sophisticated method used at Mt. Sinai, electron microscopy, he said, was too time consuming and expensive.

The Mt. Sinai researchers, who have conducted the study under a grant from the National Institute of Environmental Health Services since 1973, also investigated the powders for the presence of other metallic elements, including nickel.

With the exception of Rosemary Talc and Diaperene which contained no nickel, 16 of the powders contained from 4 to 710 parts per million (ppm) of nickel. A sample of Johnson's Baby Powder contained 2,200 ppm.

Surprised at what they regarded as a high nickel con-

tent of the powder, the researchers purchased seven more samples. Five of them had 1,800 ppm or more of nickel; two had fewer than 710 ppm. Langer said researchers "don't know if the nickel is hazardous at high levels."

Dr. F. William Sunderman, Jr., head of the department of laboratory medicine at the University of Connecticut and an expert on nickel, said: "We're trying to find out which nickel compounds do cause cancer and which don't. Certain nickel compounds are carcinogenic when inhaled; others are not."

Johnson & Johnson's associate director for public affairs, Robert Kniffin, said the nickel in the talc is "harmless" because "it is biologically inert" and won't react with body tissues.

A study revealed last September by Dr. J. C. Wagner of the Pneumoconiosis Research Unit at Penarth, Wales, raised the question about the safety of talc itself, the major ingredient in powders. Wagner found that asbestos-free talc caused fibrosis, lung scarring in the test animals "at the same rate as asbestos."

Epidemiological studies have shown that talc workers develop talcosis, another form of lung scarring, from exposure to large amounts of the mineral.

According to Selikoff, the amount of talc that must be inhaled to cause tissue scarring or cancer in humans is not known.

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ATTACHMENT 3

The New York Times Wednesday March 10, 1976

Asbestos Found In Ten Powders

Ten out of 19 body and baby powders tested at Mount Sinai Hospital here were contaminated with asbestos fibers capable of causing a rare form of chest and abdominal cancer, researchers have reported.

Dr. Arthur Rohl, who conducted the tests with Dr. Arthur Langer, said of the findings: "There is no firm evidence on low-level or intermittent exposure, such as from using talcum powder. We don't know for sure what the danger level is."

The researchers said the contamination usually was found in the talc used in the powders. Asbestos fibers can cause mesothelioma, a chest and abdominal cancer, and can also result in the scarring of lung tissue and gastro-intestinal difficulties, Dr. Rohl said.

The researchers said that 10 of the 19 American samples contained from 2 percent to 20 percent asbestos fibers with the highest concentration in ZBT Baby Powder with Baby Oil. Cashmere Bouquet Body Talc, Coty Airspun Face Powder and Rosemary Talc range from 8 percent to 20 percent asbestos fibers.

Bauer & Black Baby Talc, which is no longer on the market, had a 15 percent concentration. Other powders containing less than 5 percent asbestos were Fabergé Brut Talc, Yardley Invisible Talc, Yardley Black Label Baby Powder, Mennen Shave Talc and English Leather After Shave Talc.

The manufacturers that could be reached for comment said that they were convinced that their products were safe and that their own tests had shown no asbestos. Only the manufacturer of Rosemary could not be reached.

The products that the researchers found uncontaminated with asbestos fibers were Ammen's Medicated Powder, Avon Bird of Paradise Beauty Dust, Diaperene Medicated Body Powder; two Johnson's Baby Powders (one made here and one in Britain), Johnson's Medicated Powder, Mennen Bath Talc, Yardley After Shave Powder and Yardley Original Body Powder.

The tests at Mt. Sinai, which Federal health officials described as the country's leading research facility looking into the possible dangers of asbestos, used an electron microscope, which Heinz J. Eirmann, director of cosmetics technology in the Food and Drug Administration, said was too expensive and time-consuming for his agency to use.

The experiments at Mt. Sinai, which Dr. Rohl described as the only significant inquiry on the subject ever held, were financed by a grant from the National Institute of Environmental Health Services and were begun in 1973.